

Appl. No. 09/714,040
Amendment dated April 22, 2004
To accompany RCE in response to Advisory Action mailed March 30, 2004

REMARKS

Claims 25 and 29 remain pending in this application. Applicant submits that this response, which accompanies a request for continued examination (RCE) under 37 CFR § 1.114 is a proper submission under 37 CFR § 1.114(c). Applicant respectfully requests that the Examiner reconsider the rejection of claims in light of the comments offered below.

Claim 28 has been canceled without prejudice or disclaimer. Applicant reserves the right to pursue the subject matter of this claim in one or more continuation applications.

Claim 25 has been amended. The support for the amendment can be found throughout the specification including at page 6, lines 26 to 31 and in claim 28. Applicant submits amendment of claim 25 does not raise any issues of new matter.

Information Disclosure Statement

Applicants have received and thank the Examiner for the initialed copy of the PTO 1449 that was submitted on November 15, 2000.

35 U.S.C. § 112, First Paragraph

The Examiner has maintained the rejection of claim 25 under 35 U.S.C. § 112, first paragraph, because the Examiner contends the specification does not enable how to make the invention. The Examiner asserts in the advisory action that the arguments have been found unpersuasive because the Applicant argues with limitations not present in the claims. The Examiner further asserts that when the claims are construed with the limitations Applicant now argues with, then the rejection will be withdrawn. Applicant respectfully traverses.

Applicant submits that it is not necessary to include further limitations in the claims in order to provide for enablement of the claims. Applicants remind the examiner that the claims are drawn to compositions and not methods. Applicants submit that they have enabled at least one method of making the claimed compositions and that is all that is required to satisfy enablement. The MPEP states "as long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. § 112 is satisfied". MPEP § 2164.01(b) citing (*In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970)).

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The arguments offered by Applicant in the March 19, 2004 response asserted that the specification offers at least one method of making the invention throughout its scope.

Presumably, based on the Examiner's comments made in the March 30, 2004 advisory action:

"These arguments have been fully considered but found unpersuasive because Applicant argues with limitations not present in the claims. When the claims are construed with the limitations Applicant now argues with, then the rejection will be withdrawn."

the Examiner agrees that the specification does provide at least one method for making the invention throughout the scope of the claims. Applicant however does not agree that it is necessary to import further limitations into the claims based on the description in the specification of at least one specific method or methods of making the claimed invention.

To the extent that the Examiner is asserting that the specification, along with the ordinary level of skill in the art does not provide the necessary guidance for one of ordinary skill in the art to make a $F(ab')_2$ that is homogenous at the C-terminal end, Applicants submit the Examiner has not presented any technical reasons why other antibody fragment sequences could not be utilized in the methods of the invention to form a $F(ab')_2$ without undue experimentation. Furthermore, the MPEP states that "the presence of only one working example should never be the sole reason for rejecting claims as being broader than the enabling disclosure, even though it is a factor to be considered along with all the other factors." MPEP § 2164.02.

The only explanation provided by the Examiner is that "the specification teaches that Cys Ala Ala is the only one product that is homogenous as to the heavy chain C-terminal amino acid residues". (Office action mailed May 20, 2003; page 2). Applicant respectfully disagrees with this statement. On the contrary, the specification clearly provides for direction and guidance to one of skill in the art concerning the C terminal end of the claimed compositions. For example, a $F(ab')_2$ having Cys Ala Ala C-terminal amino acid residues was constructed (specification at least at page 30, lines 26-27). The specification also indicates that the "C-terminus of the C_H1 of Fab' is fused to the sequence Cys X X" (specification at least at page 11, lines 32-34). The specification goes on to state that X "may be any other residue such as Arg, Asp, or Pro" (specification at least at page 11, lines 34-35). The specification also states that "one or both X amino acid residues may be deleted" (specification at least at page 11, line 35). Thus, the specification provides guidance and direction to one of skill of art concerning other sequences at

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the C-terminal amino acid residues of the heavy chain. Because a specification is presumed to be enabled (MPEP § 2164.04), Applicant respectfully asserts that the Examiner has failed to establish any reasons, let alone a *prima facie* case, of why the claims are not enabled throughout their scope.

Applicants submit at the very least, the subject matter of claim 29 has been enabled by the specification. The MPEP specifically states that "a single working example in the specification for a claimed invention is enough to preclude a rejection which states that nothing is enabled since at least that embodiment would be enabled". MPEP § 2164.02. The Applicant takes issue on this point, because claim 29 has not been designated as containing allowable subject matter. Furthermore, the Examiner specifically stated that "this rejection affects all dependent claims". (Office action mailed May 20, 2003; page 2).

Based on the foregoing, Applicant respectfully requests withdrawal of the rejection on this basis.

Request for an Interview

Applicants request an interview with the Examiner and his or her supervisor upon receipt of these papers.

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SUMMARY

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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Date: April 22, 2004

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